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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/481,572	01/11/2000	JACQUELINE J. SHAN	P8061-9013	5800

7590

03/27/2002

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER 15

1651

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/481,572

Applicant(s)

SHAN ET AL.

Examin r

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-17 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/21/2002 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing since it recites a markush group which does not contain equivalent members. Angina pectoris is a specific condition whereas " a neurodegenerative disease " is not. Applicant may insert, "Alzheimer's disease" as the neurodegenerative disease, but the markush group needs to recite equivalent members. Further, "said animal" finds no proper antecedant basis. In claim 24, "the animal in need of such treatment" also fails to find proper antecedant basis.

Claims 2, 4-7, 9, 10 and 22 are confusing since they fail to further limit claim 1.

Claims 11-17 are confusing since applicant has elected an extract of *Hypericum perforatum* which contains these compounds as indicated by applicant at page 1 of the instant specification. Thus, these claims fail to further limit claim 1.

Claims 24 and 8 are substantial duplicates of one another.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-17 and 22-24 are rejected under 35 U.S.C. 102(b or e) as being anticipated by EP 847,756 (EP), Khwaja et al. or Meruelo et al. for the reasons of record and for the reasons which follow.

The teachings of EP are of record. Khwaja teaches that St. John's wort (*Hypericum perforatum*) can be administered to a patient with cardiac arrhythmia, diabetes and hypertension, see col. 23 and col. 27-28. Meruelo teaches that hypericin and pseudohypericin (which are extracts of *Hypericum perforatum*) can be administered to a patient to treat diabetes, see col. 1, col. 6 and the claims.

Applicants argue that in view of Dr. Pang's declaration the rejection of EP is moot. First, Dr. Pang's declaration states that he believes that the diseases in claim 3 of the application have no direct relationship to, and are not considered to be secondary causes of Hepatitis C infection. He never states that Hepatitis C, as a virus, cannot be treated by using a T-type calcium channel blocker (as it does not have these types of channels in its viral coat).

In fact, EP, states that hepatitis C is a disease which in 50 % of the patients can develop into a chronic infection which can then proceed to hepatic cirrhosis with its complications of portal hypertension, see col. 1 of EP.

Thus, hypertension is treated by the extract of *Hypericum perforatum* in EP.

It is inherent that the diseases listed in claim 1 will be treated since applicant has not qualified the patient to be treated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 847,756, Khwaja et al. or Meruelo et al.

The teachings of EP are of record. Khwaja teaches that St. John's wort (*Hypericum perforatum*) can be administered to a patient with cardiac arrhythmia, diabetes and hypertension, see col. 23 and col. 27-28. Meruelo teaches that hypericin and pseudohypericin (which are extracts of *Hypericum perforatum*) can be administered to a patient to treat diabetes, see col. 1, col. 6 and the claims.

It would have been obvious for one of ordinary skill in the art to treat the claimed diseases with the extract since the references are clear in their contemplation of treating the claimed diseases with the claimed extract. Such diseases are clearly taught by the references to be treated and one would clearly have been motivated to treat such diseases since they are clearly contemplated by the references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

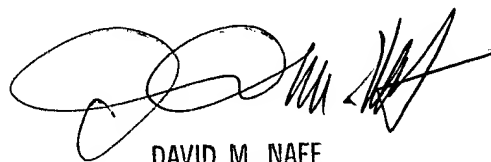
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308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
March 19, 2002



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651